



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

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3761

Appellants: Christine Carlucci and Gerard Carlucci

For: Medical Tubing Securing Device

Serial No.: 09/930,398

Filed: August 15, 2001

Group: 3761

Atty Docket: 866.0002

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September 9, 2003

Respectfully submitted,

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APPEAL BRIEF

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Real parties in interest

Christine Carlucci and Gerard Carlucci

Related appeals and interferences

None

Status of claims

Claims 1-14 are all the claims in the case. Claims 1-14 were rejected in a final action mailed on April 9, 2003. Appellants appeal the rejection of claims 1-14.

Status of amendments

No amendment was filed subsequent to final rejection.

Summary of invention

This application discloses an apparatus designed to comfortably and efficiently maintain medical tubing in place on the head of a hospitalized patient. Referring to Fig. 2, the apparatus comprises a substantially circular member (15) fabricated from an elastic material, with one or more closed loops (14) integrated therein. The circular member engages the head of the patient, and the elastic property of the circular member serves to secure it to the head of the patient comfortably without causing constriction of blood vessels or skin irritation. Preferably, the circular member is covered with soft, non-irritating material to maximize comfort. Also, the interior of the circular member may be lined with material to create friction-based contact with

the patient's skin, to help prevent slippage of the apparatus. The integrated loops can receive medical tubing such as that associated with continuous positive airway pressure (CPAP) delivery systems, nasal- and oral-gastric feeding tubes, pH probes, oral suction tubes, gastric secretion tubes and tubes used for intravenous drug delivery. Specification, page 3, lines 6-18.

This invention is particularly useful in the cases of infants born prematurely. Such patients have delicate skin which is easily irritated and bruised. Moreover, the skulls of prematurely born infants are soft and malleable and can be deformed by the use of attachment devices of the prior art. The present inventive apparatus avoids the problems of the prior art by providing a soft and flexible attachment having no hard or sharp protrusions. It will therefore not bruise or otherwise harm the vulnerable skin or skull of a very young infant.

Issue

Whether it was error to reject claims 1-14 as obvious in view of United States Patent 6,269,814 (the '814 patent) to Blaszczykiewicz et al. when the '814 patent does not teach or suggest the use of a one-piece fabric band, which is a limitation in all the claims?

Factual Background

A. The Background and Utility of the Present Invention

Prior art devices for securing medical tubing to the head of a hospitalized patient are discussed in the specification at pages 1-2. There are numerous drawbacks to these various devices. Some are prone to slippage. Slippage is generally corrected by the use of tape which

itself can cause allergic reaction or otherwise irritate the skin. The alternative to tape is to tighten the apparatus, which for patients such as premature infants can be harmful since their skulls are soft and deformable. Some of the prior art devices are prone to inadvertent disassembly of the ties, buckles, or hook-and-eye closures that are utilized to hold and secure the medical tubing.

The present invention overcomes these drawbacks by utilizing a band of soft, elastic material to encircle the head. Portions of the band are gathered to form closed loops through which tubing may be passed and thereby secured to the head. The inventive device thus does not irritate the skin, compress the skull or blood vessels, or incorporate bulky or dangerous components which can cause discomfort or injury. In addition, by virtue of the tubing loops being closed, the tubing cannot disengage from the securing device.

Referring to FIGS. 1, 2, 4, the device of the instant invention is denominated by numeral 12. Device 12 is made of a band of an elasticized, absorbent fabric and can be covered with soft, non-irritating material to maximize comfort. The interior 17 of the band may be lined with a second material such as felt or rubberized strips to create friction-based contact with the patient's skin, to assist in preventing slippage of device 12.

Device 12 includes a relatively large circular section 15 which will fit snugly to the head of the patient when slipped over the top of the skull. At least one loop 14 is adjacent to section 15, through which medical tubing such as that associated with a CPAP apparatus 10 can be inserted. As shown in FIGS. 2, 3 and 4, loop 14 can be formed by joining two points 16a and

16b, along the width w of the band, such as by stitching 13 or other non-disengagable fastening technique.

As shown by reference to FIG. 1, CPAP apparatus 18 is secured to the head of a patient 11 through use of the device 12. Apparatus 12 extends around the patient's head, above the ears. The tubing portions 10 of the CPAP apparatus are passed through loops 14 and the nasal cannulae 19 are positioned so as to fit into the nose 20 of the patient. There is no danger of the tubing portions pulling away from device 12, since loops 14 are closed.

Used as illustrated, device 12 is comfortably yet firmly seated on the patient's head and securely anchors medical tubing to the head, without the need for potentially injurious components. The device is of simple manufacture, and can be produced in a cost-effective manner.

Claim 1 of the present invention reads as follows:

A device to secure medical tubing to a body comprising a one-piece fabric band having at least a first closed loop and a second closed loop, wherein the first closed loop fits elastically around a portion of the body and the second closed loop is capable of receiving and holding medical tubing close to the body.

The remainder of the claims are set out in the Appendix attached hereto. They all include the limitation of a one-piece fabric band.

B. The '814 Patent

The invention of the '814 patent is a sleep apnea headgear comprised of a series of stretchable fabric pieces connected to each other by hook-and-loop attachments. One inverted T-shaped piece (12) is connected to a second inverted T-shaped piece (14), such that the legs of the

T (24, 46) are connected over the top of the head and the ends of cross-piece (30) of the first T-shaped piece is adjustably connected to the ends of cross-piece (44) of the second T-shaped piece to encircle the head. A chinstrap (32) is provided to further secure the apparatus.

Argument: The Examiner's Rejection Was Erroneous Because the '814 Patent Teaches Away from the Use of a One-Piece Fabric Band

The examiner rejected claims 1-14 under 35 U.S.C. § 103 as obvious in view the '814 patent, finding that it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the fabric band of the '814 patent in one piece. This rejection is erroneous.

The stated purpose of the '814 patent was to provide an adjustable headgear for sleep apnea sufferers. '814 patent, col. 1, line 45-49 and col. 2, lines 43-44. The '814 patent discloses that the fabric of the headgear should be stretchable, col. 1, line 54. In order to obtain the desired adjustability, the '814 patent teaches the latitudinal legs 44 of the front T-shaped piece 14 contains slots 58 to receive the latitudinal legs 22 of the rear T-shaped piece 12. On the ends of latitudinal legs 22 are hook pads 38. Once latitudinal legs 22 are slipped through slots 58, hook pads 38 can be secured to various locations along latitudinal leg 44.

The manner of assembling and of adjusting the headgear of the '814 patent is set out in the patent at column 3, lines 14-33. When fully assembled, "various size adjustments are possible by changing the location at which hook pad 48 connects to longitudinal leg 24, changing the locations at which hook pads 38 connect to latitudinal leg 44, and changing the locations at which chinstrap 16 is captured by fastening means 32." Col. 3, lines 29-33.

The examiner rejected claims 1-14 as obvious in view of the '814 patent, citing *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893) to support the proposition that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. This case, however, is inapposite.

In *Howard*, the invention at issue was for a stove which contained a grate which was cast in one piece. In the prior art, however, was a stove having a grate which had been cast in two pieces and the two pieces were bolted together during manufacture. The Court examined the functions of the various elements of the stoves. The one-piece grate functioned the same as the bolted-together grate of the prior art. In such a case, there is no patentable invention. *Id.* at 169-170.

In this case, however, the one-piece fabric band as claimed in claims 1-14 of the present application does not function as does the headgear of the '814 patent. It is not adjustable along its length, as is the head band of the '814 patent. Instead, it fits elastically, exerting a continuous pressure which secures it to the head.

In view of the stated purpose of the invention of the '814 patent to provide an adjustable headgear, it would not be obvious to one of ordinary skill in the art to substitute a one-piece fabric band for the two T-shaped piece headgear of the '814 patent. Such a substitution would destroy the purpose of the '814 headgear which was designed to be adjustable along the headband area.

The examiner has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Piasecki*, 745 F.2d 1468, 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984). This

burden can be satisfied only when the examiner presents evidence, by means of some teaching, suggestion, or inference either in the applied prior art or generally available knowledge, that would appear to have suggested the claimed subject matter to a person of ordinary skill in the art or would have motivated a person of ordinary skill in the art to combine the applied references in the proposed manner to arrive at the claimed invention. *Carella v. Starlight Archery Pro Line Col.*, 804 F.2d 135, 140, 231 U.S.P.Q. 644, 647 (Fed. Cir. 1986). The examiner has not met his burden in this case. There does not appear from the examiner's rejection any basis for concluding that combining a one-piece fabric band into the '814 headgear would be obvious to one skilled in the art. There is no suggestion in the '814 patent that it would be desirable to substitute a continuously elastic headband for the latitudinal legs 12 and 14 of the '814 patent. Nor is there any motivation to make such a substitution. Indeed, in disclosing the use of two adjustment points in stretchable fabric, it appears that the '814 patent teaches away from the use of a one-piece, continuous pressure, fabric band.

The proposed combination appears to be merely a reconstruction of the present invention using hindsight. This is impermissible. As stated in *Grain Processing Corp. v. American Maize-Products Co.*, 840 F.2d 902, 907 (Fed. Cir. 1988):

When resolving an obviousness issue, "the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination." *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed. Cir. 1984). Care must be taken to avoid hindsight reconstruction by using "the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit." *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1012, 217 USPQ 193, 199 (Fed. Cir. 1983).


Because there is no teaching or suggestion to support the combination on which the rejection is based, it is respectfully submitted that the rejection of the claims was erroneous and should be reversed.

Conclusion

In view of the foregoing, it is respectfully requested that the rejection of claims 1-14 be reversed, and that the claims be allowed to proceed to issue.

September 9, 2003

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Appendix: Claims Involved in the Appeal

1. A device to secure medical tubing to a body comprising a one-piece fabric band having at least a first closed loop and a second closed loop, wherein the first closed loop fits elastically around a portion of the body and the second closed loop is capable of receiving and holding medical tubing close to the body.
2. A device according to claim 1 wherein the portion of the body around which the first closed loop fits is a head.
3. A device according to claim 1 wherein fabric band is covered with a soft, non-irritating material.
4. A device according to claim 1 wherein the fabric band is at least partially lined with a friction creating material.
5. A device according to claim 1 wherein the closed loops are formed by stitching.
6. A device to secure medical tubing to a body comprising a one-piece fabric band having a first closed loop, a second closed loop and a third closed loop, wherein the first closed loop fits elastically around a portion of the body and the second and third closed loops are capable of receiving and holding medical tubing close to the body.
7. A device according to claim 6 wherein the portion of the body around which the first closed loop fits is a head.
8. A device according to claim 6 wherein fabric band is covered with a soft, non-irritating material.

9. A device according to claim 6 wherein the fabric band is at least partially lined with a friction creating material.
10. A device according to claim 6 wherein the closed loops are formed by stitching.
11. A device to secure medical tubing to a body comprising a one piece fabric band having a width wherein stitching along the width joins portions of the band to form a first closed loop, a second closed loop and a third closed loop, and wherein the first closed loop fits elastically around a portion of the body and the second and third closed loops are capable of receiving and holding medical tubing close to the body.
12. A device according to claim 11 wherein the portion of the body around which the first closed loop fits is a head.
13. A device according to claim 11 wherein fabric band is covered with a soft, non-irritating material.
14. A device according to claim 11 wherein the fabric band is at least partially lined with a friction creating material.